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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,301	02/05/2002	Radoje Drmanac	27373/38132	9617

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MARSHALL, GERSTEIN & BORUN
6300 SEARS TOWER
233 SOUTH WACKER
CHICAGO, IL 60606-6357

EXAMINER

SIEW, JEFFREY

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 07/02/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,301

Applicant(s)

DRMANAC, RADOJE

Examiner

Jeffrey Siew

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-121 is/are pending in the application.
- 4a) Of the above claim(s) 102-121 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 102-121 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 8.

Priority

2. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant

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application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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Specification

3. The application references US serial numbers (see e.g. page 21 line 24). The current status of referenced applications should be updated.
4. Figure 1 is described in the Brief Description of the Drawings but the drawings actually contains Figures 1A to 1C.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 47-97,99 & 101 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,401,267. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 47-97,99 & 101 are drawn to a method of identifying at least one nucleotide

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sequence comprising connecting nucleotide sequence of detected labeled probe with respective immobilized probe.

Claims 1-36 of US 6,401,267 are drawn to method of determining sequence by assembling the nucleic acid sequence from said overlapping sequences identified which represents a species of the genus claims 47-101 in that claims 1-36 are drawn to identification of stretch of nucleotides and genus claims include the scope that includes at least one nucleotide identified.

6. Claims 98 & 100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 6,401,267 in further view of Duck et al (US4,876,187 Oct. 24, 1989).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 98 & 101 are drawn to a method of identifying at least one nucleotide sequence comprising connecting nucleotide sequence of detected labeled probe with respective immobilized probe with added limitation of RNase or uracil glycosylase treatment.

As described previously, claims 1-36 of US 6,401,267 are drawn to method of determining sequence by assembling the nucleic acid sequence from said overlapping sequences identified. Claims 37-40 are drawn to kit with sixmer probes.

Claims 1-40 are not drawn to RNase or uracil glycosylase.

Duck et al teach RNase and uracil glycosylase for washing unhybridized probes (see col. 9 lines 35-40 & col. 11 lines 16-45).

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One of ordinary skill in the art would have been motivated to apply Duck et al's Rnase and uracil glycosylase treatment to method and kit claims 1-40 of US6,401,267 in order to remove unhybridized sequences. It would have been prima facie obvious to apply Duck et al's treatment to claims 1-40 in order to remove sequences in order to regenerate surfaces of support.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47-55,57,59-75,79-82,84-91,93-96,101 rejected under 35 U.S.C. 102(b) as being anticipated by Landegren et al (4,988,617 Jan. 29, 1991).

Landegren et al teach a method of determining nucleotide sequence in which a target nucleic acid is contacted with a set of immobilized oligonucleotide probes and one labeled probe under a set of probes, covalently joining immobilized probe and labeled probe, detecting label and identifying sequence (see whole doc. esp.col. 11 line 46-col. 12 line 27). They teach using ligase (see col. 9 line 36). They teach using various different probes to detect various loci (see col.12 line41-65). They teach using stringent washing (see col. 7 line 35-65). They also teach testing mRNA sequences (see col. 5 line 51-col. 6 line 17). They teach simultaneous and sequential steps in annealing and ligation (see col. 6 lines 52-60). They also teach using 9mer or

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10mer size probes and target of 19 nucleotides or longer (see col. 8 lines 20-29). They teach using various probes such as fluorescein that permit multicolor analysis and radioisotopes (see col. 8 lines 47-68). The solid support may be nylon or dextran supports or agarose beads (see col. 11 line 60 & col. 12 line 25).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 56,58,76-78, 97,99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landegren et al (4,988,617 Jan. 29, 1991 in view of Cantor (US5,503,980 April 2, 1996).

The teachings of Landegren are described previously (note especially the immobilization on various solid supports on col. 11 lines 58-col. 12 line 27).

Landegren et al explicitly do not teach sequencing chip, RNA probes or fragmentation.

Cantor teach sequencing chip (see col. 2 line 40). They also teach using RNA probes with uracil (see col. 5 lines 25-55). They teach fragmenting target nucleic acids with restriction enzymes (see col. 9 line 13-29).

One of ordinary skill in the art would have been motivated to apply Landegren et al's immobilized probes onto Cantor's sequencing chip in order to automate the detection of

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different targets. The use of a sequencing chip allows simultaneous and automated detection of different probes on an array. It would have been prima facie obvious to apply Landegren et al's detection method to Cantor's chip in order to simultaneously analyze multiple different targets.

Moreover, it would have been prima facie obvious to apply Cantor's teaching of RNA probes and fragmentation in order to sequence large pieces of nucleic acids and sequence RNA.

9. Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landegren et al (4,988,617 Jan. 29, 1991 in view of Southern (WO89/10977 16 November 1989).

The teachings of Landegren are described previously (note especially the immobilization on various solid supports on col. 11 lines 58-col. 12 line 27).

Landegren do not teach glass supports.

Southern teach glass supports (see page 11 line 25).

One of ordinary skill in the art would have been motivated to apply Southern's glass supports to Landegren's probes in order to increase the number of bound probes. Southern teaches that the resolution of probes on glass supports is around 10 microns. It would have been prima facie obvious to apply Landegren's probes to Southern's glass support to increase the number of immobilized probes per area.

10. Claims 98 & 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landegren et al (4,988,617 Jan. 29, 1991 in view of Duck et al (US4,876,187 Oct. 24, 1989).

The teachings of Landegren et al are described previously.

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Landegren et al do not teach RNase or uracil glycosylase.

Duck et al teach RNase and uracil glycosylase for washing unhybridized probes (see col. 9 lines 35-40 & col. 11 lines 16-45).

One of ordinary skill in the art would have been motivated to apply Duck et al's RNase and uracil glycosylase treatment to Landegren et al's method of detection in order to remove unhybridized sequences. It would have been prima facie obvious to apply Duck et al's treatment to Landegren et al's method in order to remove sequences in order to regenerate surfaces of support.

SUMMARY

11. No claims allowed.

CONCLUSION

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

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Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.


JEFFREY SIEW
PRIMARY EXAMINER

June 29, 2003